Docket No.: 290494.122US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ezio Ghigo et al.	Art Unit:	1646
Appl. No.:	10/595,485	Examiner:	Not Yet Assigned
Filing Date:	September 6, 2007	Conf. No.:	1304
Title:	USE OF GHRELIN AND UNACYLATED GHRELIN COMPOSITIONS IN INSULIN-RELATED DISEASE CONDITIONS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CORRECTED FILING RECEIPT

Dear Sir:

Attached is a copy of the Filing Receipt received from the U.S. Patent and Trademark Office in the above-referenced application. The number of independent claims is listed incorrectly. The correct number of independent claims is three (3), not two (2). A marked-up copy of the Filing Receipt is submitted herewith to reflect the change. Furthermore, a copy of the claims in their present form is also attached. Note that claims 1, 30, and 54 are independent.

It is requested that a corrected filing receipt be issued.

It is believed that no fee is required as this discrepancy was due to U.S. Patent and Trademark Office error, however, if a fee is required, the Commissioner is authorized to charge such fee to Deposit Account No. 08-0219.

Respectfully submitted,

Date: February 6, 2009

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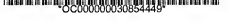
APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
10/595,485	09/06/2007	1646	3380	290494-999US1	57	~~2~~ 3

CONFIRMATION NO. 1304

23483
WILMERHALE/BOSTON
60 STATE STREET
BOSTON, MA 02109

FILING RECEIPT



Date Mailed: 07/14/2008

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

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Power of Attorney: The patent practitioners associated with Customer Number 23483

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/CA04/01858 10/22/2004
which claims benefit of 60/513,540 10/24/2003

Foreign Applications

If Required, Foreign Filing License Granted: 07/08/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 10/595,485**

Projected Publication Date: 10/23/2008

Non-Publication Request: No

Early Publication Request: No

Title

Use of Ghrelin and Unacylated Ghrelin Compositions in Insulin-Related Disease Conditions

Preliminary Class

514

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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Amendments to the Claims

1. (Original) A method of altering an insulin-associated parameter in a subject, said method comprising administering to said subject a ghrelin or analog thereof; and an unacylated ghrelin or analog thereof.

2. (Original) The method of claim 1, wherein said method comprises administering to said subject a composition comprising a ghrelin or analog thereof; and an unacylated ghrelin or analog thereof.

3. (Original) The method of claim 2 wherein said composition further comprises a pharmaceutically acceptable carrier.

4. (Original) The method of claim 1, wherein said insulin-associated parameter is selected from the group consisting of:

   (a) insulin level;

   (b) insulin resistance;

   (c) free fatty acid level;

   (d) insulin activity;

   (e) insulin sensitivity; and

   (f) any combination of (a) to (e).

5. (Original) The method of claim 1, wherein said alteration of an insulin-associated parameter is selected from the group consisting of:

   (a) a decrease in insulin level;

   (b) a decrease in insulin resistance;

   (c) a decrease in free fatty acid level; and

   (d) any combination of (a) to (c).

6. (Original) The method of claim 1, wherein said method is for preventing or treating an insulin-associated condition.

7. (Original) The method of claim 4, wherein said insulin-associated parameter is insulin resistance.

8. (Original) The method of claim 7, wherein said insulin resistance is associated with a state or condition selected from the group consisting of:

   (a) postprandial state;

   (b) reduced growth hormone level;

   (c) reduced growth hormone activity;

   (d) obesity;

   (e) diabetes;

   (f) intravenous nutrition due to critical illness;

   (g) metabolic syndrome X; and

   (h) any combination of (a) to (g).

9. (Original) The method of claim 8, wherein said state or condition is reduced growth hormone level, activity, or both.

10. (Original) The method of claim 9, wherein said reduced growth hormone level, activity, or both are associated with a condition selected from the group consisting of:

   (a) obesity;

   (b) aging;

   (c) pituitary gland deficiency;

   (d) intravenous nutrition; and

   (e) any combination of (a) to (d).

11. (Original) The method of claim 8, wherein said state or condition is diabetes.

12. (Original) The method of claim 11, wherein said diabetes is selected from the group consisting of type I diabetes and type II diabetes.

13. (Original) The method of claim 12, wherein said diabetes is type I diabetes.

14. (Original) The method of claim 13, said method is for preventing or treating the dawn phenomenon.

15. (Original) The method of claim 1, wherein said administration of said ghrelin or analog thereof and said unacetylated ghrelin or analog thereof is sequential.

16. (Original) The method of claim 1, wherein said administration of said ghrelin or analog thereof and said unacetylated ghrelin or analog thereof is simultaneous.

17. (Original) The method of claim 1, wherein said ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 1 and a fragment thereof.

18. (Original) The method of claim 17, wherein said ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 1.

19. (Original) The method of claim 1, wherein said unacylated ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 2 and a fragment thereof.

20. (Original) The method of claim 19, wherein said unacylated ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 2.

21. (Original) The method of claim 1, wherein said analog of ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 3 and a fragment thereof.

22. (Original) The method of claim 21, wherein said analog of ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 3.

23. (Original) The method of claim 1, wherein said analog of unacylated ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 4 and a fragment thereof.

24. (Original) The method of claim 23, wherein said analog of unacylated ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 4.

25. (Original) The method of claim 1, wherein said ghrelin or analog thereof and said unacylated ghrelin or analog thereof is administered through a route selected from the group consisting of intravenous, oral, transdermal, subcutaneous, mucosal, intramuscular, intranasal, intrapulmonary, parenteral, intrarectal and topical.

26. (Original) The method of claim 1, wherein said ghrelin or analog thereof is administered at a dose of about 1 μg/kg.

27. (Original) The method of claim 1, wherein said unacetylated ghrelin or analog thereof is administered at a dose of about 1 μg/kg.

28. (Original) The method of claim 1, wherein said subject is a mammal.

29. (Original) The method of claim 1, wherein said subject is human.

30. (Original) A composition comprising a ghrelin or analog thereof and an unacylated ghrelin or analog thereof.

31. (Original) The composition of claim 30, said composition further comprising a pharmaceutically acceptable carrier.

32. (Original) The composition of claim 30, wherein said ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 1 and a fragment thereof.

33. (Original) The composition of claim 32, wherein said ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 1.

34. (Original) The composition of claim 30, wherein said unacylated ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 2 and a fragment thereof.

35. (Original) The composition of claim 34, wherein said unacylated ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 2.

36. (Original) The composition of claim 30, wherein said analog of ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 3 and a fragment thereof.

37. (Original) The composition of claim 36, wherein said analog of ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 3.

38. (Original) The composition of claim 30, wherein said analog of unacylated ghrelin comprises an amino acid sequence substantially identical to a sequence selected from the group consisting of SEQ ID NO: 4 and a fragment thereof.

39. (Original) The composition of claim 38, wherein said analog of unacylated ghrelin comprises a peptide having the amino acid sequence of SEQ ID NO: 4.

40. (Original) The composition of claim 30, wherein said composition is adapted for administration by a route selected from the group consisting of intravenous, oral, transdermal, subcutaneous, mucosal, intramuscular, intranasal, intrapulmonary, parenteral, intrarectal and topical.

41. (Original) The composition of claim 30, wherein said composition is adapted for administration of said ghrelin or analog thereof at a dose of about 1 μg/kg.

42. (Original) The composition of claim 30, wherein said composition is adapted for administration of said unacetylated ghrelin or analog thereof at a dose of about 1 μg/kg.

43. (Original) The method of claim 2, wherein said insulin-associated parameter is selected from the group consisting of:

(a) insulin level;

(b) insulin resistance;

(c) free fatty acid level;

(d) insulin activity;

(e) insulin sensitivity; and

(f) any combination of (a) to (e).

44. (Original) The method of claim 43, wherein said alteration of an insulin-associated parameter is selected from the group consisting of:

(a) a decrease in insulin level;

(b) a decrease in insulin resistance;

(c) a decrease in free fatty acid level; and

(d) any combination of (a) to (c).

45. (Original) The method of claim 2, wherein said method is for preventing or treating an insulin-associated condition.

46. (Original) The method of claim 45, wherein said insulin-associated parameter is insulin resistance.

47. (Original) The method of claim 46, wherein said insulin resistance is associated with a state or condition selected from the group consisting of:

(a) postprandial state;

(b) reduced growth hormone level;

(c) reduced growth hormone activity;

(d) obesity;

(e) diabetes;

(f) intravenous nutrition due to critical illness;

(g) metabolic syndrome X; and

(h) any combination of (a) to (g).

48. (Original) The method of claim 47, wherein said state or condition is reduced growth hormone level, activity, or both.

49. (Original) The method of claim 48, wherein said reduced growth hormone level, activity, or both are associated with a condition selected from the group consisting of:

(a) obesity;

(b) aging;

(c) pituitary gland deficiency;

(d) intravenous nutrition; and

(e) any combination of (a) to (d).

50. (Original) The method of claim 47, wherein said state or condition is diabetes.

51. (Original) The method of claim 50, wherein said diabetes is selected from the group consisting of type I diabetes and type II diabetes.

52. (Original) The method of claim 51, wherein said diabetes is type I diabetes.

53. (Original) The method of claim 52, said method is for preventing or treating the dawn phenomenon.

54. (Original) A package comprising a ghrelin or analog thereof and an unacylated ghrelin or analog thereof.

55. (Original) The package of claim 54, further comprising instructions for altering an insulin-associated parameter in a subject.

56. (Original) A package comprising the composition of claim 30.

57. (Original) The package of claim 56, said package further comprising instructions for altering an insulin-associated parameter in a subject.

58. - 86. (Canceled)